

WHAT IS CLAIMED IS:

1. A pharmaceutical formulation of erythropoietin comprising:
 - (a) a pH buffering agent;
 - (b) a stabilizing amount of a sorbitan mono-9-octadecenoate poly(oxy-1,2-ethanediyl) derivative;
 - (c) a stabilizing amount of an amino acid;
 - (d) a pharmaceutical quantity of erythropoietin; and

wherein the formulation does not contain urea or a human blood product.
- 10 2. The formulation of claim 1 wherein the formulation is aqueous.
- 15 3. The formulation of claim 1 wherein the pH buffering agent is in a range of about 10mM to about 30mM.
- 20 4. The formulation of claim 1 wherein the pH buffering agent provides a pH range from about 5 to about 8.
- 25 5. The formulation of claim 3 wherein the pH buffering agent provides a pH range from about 6 to about 7.5.
6. The formulation of claim 5 wherein the pH buffering agent provides a pH of about 6.9
- 25 7. The formulation of claim 1 wherein the pH buffering agent is selected from a group consisting of sodium phosphate monobasic/sodium phosphate dibasic, sodium citrate/citric acid, and sodium acetate/acetic acid.
- 30 8. The formulation of claim 7 wherein the pH buffering agent is in a range of about 10mM to about 30mM.

9. The formulation of claim 8 wherein the pH buffering agent provides a pH range from about 5 to about 8.

5 10. The formulation of claim 9 wherein the pH buffering agent provides a pH range from about 6 to about 7.5.

11. The formulation of claim 10 wherein the pH buffering agent provides a pH of about 6.9.

10 12. The formulation of claim 1 wherein the sorbitan mono-9-octadecenoate poly(oxy-1,2-ethanediyl) derivative is selected from the group consisting of polysorbate 80 and polysorbate 20.

15 13. The formulation of claim 1 wherein the amino acid is glycine.

14. The formulation of claim 1 further comprising a tonicity agent, wherein the tonicity agent is selected from a group consisting of sodium chloride, mannitol, glycine, glucose and sorbitol.

20 15. The formulation of claim 1 wherein the pharmaceutical quantity of erythropoietin is formulated to provide a quantity per dose in the range of about 1000IU to about 100,000IU erythropoietin.

25 16. The formulation of claim 15 wherein the pharmaceutical quantity of erythropoietin is formulated to provide a quantity per dose selected from the group consisting of about 2,000IU, about 3,000IU, about 4,000IU, about 10,000IU, about 20,000IU, about 25,000IU or about 40,000IU.

30 17. The formulation of claim 16 wherein the sorbitan mono-9-octadecenoate poly(oxy-1,2-ethanediyl) derivative is polysorbate 80 and the amino acid is glycine.

18. The formulation of claim 17 wherein polysorbate is in the range of about 0.01 to about 1.0 g /L and glycine is in the range of about 1 g/L to about 50 g/L.

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19. The formulation of claim 18 further comprising a tonicity agent, wherein the tonicity agent is selected from the group consisting of sodium chloride, mannitol, glycine, glucose and sorbitol.

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20. The formulation of claim 19 wherein the pH buffering agent is selected from a group consisting of sodium phosphate monobasic/sodium phosphate dibasic, sodium citrate/citric acid, and sodium acetate/acetic acid.

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21. The formulation of claim 20 wherein the pH buffering agent provides a pH in the range of about pH 5 to about pH 8.

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22. A pharmaceutical formulation of erythropoietin comprising:

- (a) a pH buffering agent;
- (b) a stabilizing amount of sorbitan mono-9-octadecenoate
- (c) a stabilizing amount of an amino acid;
- (d) a pharmaceutical quantity of erythropoietin;
- (e) a tonicity agent; and

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wherein the formulation does not contain urea or a human blood product.

23. The formulation of claim 22 wherein the formulation is aqueous.

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24. The formulation of claim 22 wherein the pH buffering agent is in a range of about 10mM to about 30mM.

25. The formulation of claim 22 wherein the pH buffering agent provides a pH range from about 5 to about 8.

26. The formulation of claim 24 wherein the pH buffering agent provides a pH range from about 6 to about 7.5

5 27. The formulation of claim 26 wherein the pH buffering agent provides a pH of about 6.9.

10 28. The formulation of claim 22 wherein the pH buffering agent is selected from a group consisting of sodium phosphate monobasic/sodium phosphate dibasic, sodium citrate/citric acid, and sodium acetate/acetic acid.

29. The formulation of claim 28 wherein the pH buffering agent is in a range of about 10mM to about 30mM.

15 30. The formulation of claim 29 wherein the pH buffering agent provides a pH range from about 5 to about 8.

31. The formulation of claim 30 wherein the pH buffering agent provides a pH range from about 6 to about 7.5.

20 32. The formulation of claim 31 wherein the pH buffering agent provides a pH of about 6.9.

25 33. The formulation of claim 22 wherein the sorbitan mono-9-octadecenoate poly(oxy-1,2-ethanediyl) derivative is selected from the group consisting of polysorbate 80 and polysorbate 20.

34. The formulation of claim 22 wherein the amino acid is glycine.

30 35. The formulation of claim 22 wherein the tonicity agent is selected from a group consisting of sodium chloride, mannitol, glycine, glucose and sorbitol.

36. The formulation of claim 22 wherein the pharmaceutical quantity of erythropoietin is formulated to provide a quantity per dose in the range of about 1000IU to about 100,000IU erythropoietin.

5 37. The formulation of claim 36 wherein the pharmaceutical quantity of erythropoietin is formulated to provide a quantity per dose selected from the group consisting of about 2,000IU, about 3,000IU, about 4,000IU, about 10,000IU, about 20,000IU, about 25,000IU or about 40,000IU.

10 38. The formulation of claim 37 wherein the sorbitan mono-9-octadecenoate poly(oxy-1,2-ethanediyl) derivative is polysorbate 80 and the amino acid is glycine.

15 39. The formulation of claim 38 wherein polysorbate is in the range of about 0.01 to about 1.0 g/L and glycine is in the range of about 1 g/L to about 50 g/L.

20 40. The formulation of claim 39 further comprising a tonicity agent, wherein the tonicity agent is selected from the group consisting of sodium chloride, mannitol, glycine, glucose and sorbitol.

41. The formulation of claim 40 wherein the pH buffering agent is selected from a group consisting of sodium phosphate monobasic/sodium phosphate dibasic, sodium citrate/citric acid, and sodium acetate/acetic acid.

25 42. The formulation of claim 41 wherein the pH buffering agent provides a pH in the range of about pH 5 to about pH 8.